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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/306,780 05/07/99 TAKEMURA

F 2084-0046-0D

EXAMINER

022850 HM12/0810
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ART UNIT

PAPER NUMBER

1645

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08/10/01

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Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/306,780

Applicant(s)

TAKEMURA ET AL.

Examiner

Ja-Na A Hines

Art Unit

1645

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 29 May 2001.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☐ Claim(s) 17-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) 17-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Continued Prosecution Application

1. The request filed on May 29, 2001 for a Continued Prosecution Application (CPA) under 37 CFR 1.53(d) based on parent Application No. 09/306,780 is acceptable and a CPA has been established. An action on the CPA follows. Claims 17-32 are pending.

Priority

2. ⁹/₈ Applicant stated that a claim to priority and amendment were filed on May 7, 1999. However, the parent application has become abandoned, the expression "now abandoned" should follow the filing date of the parent application.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. ⁹/₅ Claims 17-32 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. Claims 17 and 25 are rejected under 35 U.S.C. 112, second paragraph, for omitting essential method steps. The claims are drawn to an immunoassay for assaying an antigen and an agglutination assay. However, the claims lack a contact step, a detection step, and a correlation step. For instance, in claim 17, the omitted steps are: There is no contact step which contacts the assayed antigen with the nucleic acid-bound polypeptide or detection species. There is no detection step which detects either the antigen or the nucleic acid-bound polypeptide. The claims

do not recite the use of any detectable agents which may bind, to aid in assaying for an antigen. Finally, there is no correlation step which correlates assaying for the antigen with the detection of the nucleic acid-bound polypeptide.

4. Claims 23-24 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 23-24 and 31-32 are rejected under 35 U.S.C. 112, second paragraph, for being unclear. The recitation "wherein said nucleic acid binding motif has an amino acid sequence with SEQ ID NO:2" is unclear. Does applicant intend a recitation stating the amino acid sequence as set forth in SEQ ID NO:2 or something else?

Response to Arguments

5. Applicant's arguments filed May 29, 2001 have been fully considered but they are not persuasive.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 17-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Weiner et al., is maintained. Applicant argues that Takahara et al., teaches a method of gene transfer which would not have suggested performing any immunoassay, since the reference suggest binding a nucleic acid to a polypeptide for a completely unrelated purpose. However, Takahara et al., states clear motivation for using the nucleic acid-bound polypeptide in

other formats. Takahara teaches linking the nucleic acid to a wide variety of polypeptides including antibodies which can specifically bind to a corresponding antigen (page 2 lines 5-14). Thus, Takahara et al., provides motivation for using a known product, i.e., the nucleic acid-bound polypeptide, wherein the nucleic acid can be bound with an antibody. No more than routine skill would have been required to use antibody bound products in known immunoassay.

In response to applicant's argument that Takahara et al., teaches a method of gene transfer and this would not have suggested performing any immunoassay, since the reference suggest binding a nucleic acid to a polypeptide for a completely unrelated purpose, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985).

In response to applicant's argument that the basic idea of the instant applicant is to intentionally change the performance of the peptide in an immunoassay so as to increase the immunological reactivity of the peptide by using a nucleic acid; whereas Takahara et al., in view of Weiner et al., do not involve changing the properties of the peptide., a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art product is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of using, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

Applicants argue that one of skill in the art would be very concerned about the DNA having a negative effect on the antigenicity of the peptide. Applicants state that one of skill in the art would be concerned about certain aspects, however, in the absence of scientific data teaching away from using the known nucleic acid bound polypeptides, statements about concern are not persuasive. Furthermore, Takahara et al., teaches an advantage to having the nucleic acid bound to the polypeptide. Takahara et al., teaches that the nucleic acid is bound to suppress the decomposition of the nucleic acid (page 2 lines 41-42).

In response to applicant's argument that the references fail to show certain unexpected properties of applicant's invention, it is noted that the features upon which applicant relies, i.e., that the HCV-positive serum could only be detected when the polypeptide/nucleic acid conjugate 120NA(+)) was fixed on gelatin particles is not recited in the rejected claims. Also not recited in the claims are the increased antigenic properties of the polypeptide to the antibody. There is no recitation in the claims drawn to increased sensitivity of the antibody; nucleic acid-bound 120NA recombinant proteins; specific antibodies; specific core antigens of HCV or specific immunoassay techniques such as gelatin particle usage. The claims of the instant application are broad and are therefore not interpreted to be limited by the sensitivity and unexpected results applicants refer to since these features are not claimed. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

7. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Weiner et al., in further view of Ono et al., is maintained. Takahara et al., and Weiner et al., have been discussed above. Even though applicant has not specifically addressed Ono et al., it would have been obvious at the time of applicant invention to have used the Ono et al., hepatitis virus sequence, in the immunoassay of Takahara et al., and Weiner et al., because Ono et al., teaches the complete nucleotide sequence which is important in the understanding of the genetic system.

8. Claims 25-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Gibbons is maintained. Takahara et al., has been discussed above. Even though applicant has not specifically addressed Gibbons, it would have been obvious to use the agglutination assay of Gibbons with the antigen comprising a nucleic acid bound antibodies, a type of polypeptide as taught by Takahara et al., because Gibbons teaches binding pairs include antigens and antibodies or complementary nucleic acid strands; that agglutination assays do not require expensive detection equipment; and can be readily adaptable to instrumental quantitation.

9. Claims 31 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Takahara et al., in view of Gibbons, in further view of Ono et al., is maintained. Takahara et al., and Gibbons, have been discussed above. However, no more than routine skill would have been required at the time of applicant invention to have used the Ono et al., hepatitis virus sequence,

in the immunoassay of Takahara et al., and Gibbons, because Ono et al., teaches the complete nucleotide sequence which is important in the understanding of the genetic system.

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na Hines whose telephone number is (703) 305-0487. The examiner can normally be reached on Monday through Thursday from 6:30am to 4:00pm. The examiner can also be reached on alternate Fridays.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Ja-Na Hines



August 7, 2001


LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
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